Influenza Vaccine Development in Vietnam: Technology assessment

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PATH
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Vietnam case study outline

- Capacity building framework
- Influenza vaccine development in Vietnam
- Technology assessment
- Path forward

Conducting serology survey in the field
Photo credit: Huong Vu - PATH

Framework for capacity building in Vietnam

- Strengthen capacity of manufacturers for influenza vaccine production
- Strengthen capacity of local institutions in conducting/ managing standard clinical trials
- Strengthen capacity of National Regulatory Authority (MOH) for ensuring vaccine quality and clarifying guidelines for vaccine licensure
- Identify strategies for sustainable production and use of influenza vaccine in Vietnam (seasonal influenza)

Ongoing influenza activities in Vietnam

- Strategies to control pandemic influenza have been a high priority for many years in response to repeated human cases of H5N1
  - Strongly supported by the governments of Vietnam, the United States, WHO and others
  - Surveillance system to identify prevalence and seasonality of influenza was established in collaboration with the US CDC
  - Efforts to draft short- and long-term strategies for pandemic and seasonal influenza management
  - Progress towards identifying gaps and establishing steps to towards vaccine licensure and use

Human influenza vaccine development

Four groups with strong interest in producing human influenza vaccine

- rgH5N1 seed virus (now H1N1)
- Whole-inactivated virus
- Alum adjuvant
- **Different substrates**

Technology assessment

Objective: Evaluate each manufacturer to prioritize efforts to accelerate production of influenza vaccine.

- Human vaccine production experience
- Influenza vaccine development experience
- Vaccine substrate
  - Regulatory guidelines
  - Practicality for influenza vaccine production
  - Expertise / training available for further development
- Comments from the Vietnam Ministry of Health
- Estimated timeline for production of CTM
- Long-term plan for sustainable influenza vaccine production

Company A

- Experienced in human vaccine production and export
- Substrate: Primary monkey kidney cells
  - Low scale, low yield cell factories
  - Challenging regulatory pathway
  - Early stage consideration for Vero or MDCK cells
- Completed the production process and manufacture of H5N1 clinical lots, conducted Phase 1/2 trials
- Pilot capacity target: 1.2M doses/year
- Plans for scale up: 20M+ doses/year
- Intermediate lead time to clinic (3 – 5 years)

Company B

- Experienced in human vaccine production and export
- Substrate: Embryonated chicken eggs
  - Building sustainable, biosecure poultry facility for eggs
- Produced more than 5 lots of H5N1 that met WHO requirements and now over 8 lots of H1N1
- Completed immunogenicity in animals for both H5N1 and H1N1
- New manufacturing facility for production of influenza vaccine complete and undergoing validation
- Full capacity targeted to 1.5M to 3M doses/year
- Short lead time to clinic (1 – 2 years)

Company C

- Previous production of BCG vaccine
  - Research facility, no manufacturing site, no tech transfer plan or business model for influenza vaccine production
- Substrate: Vero cells
  - Shaker flask / roller bottle scale
- Completed production process for H5N1
- Completed preclinical stage to show immunogenicity in animals
- Long lead time to clinic (5+ years)

Company D

- Experienced in production and export of polio vaccine
- Substrate: Undecided.
  - Plans to explore either CEF or Vero cells
- Very early research stage, new interest due to H1N1 situation
- No facility for influenza vaccine production
  - Long-term plans for influenza vaccine unclear
- Long lead time to clinic (5+ years)

Path forward

- Reviewed assessment with representatives from Vietnam MOH, BARDA and WHO
- Company B with egg-based manufacturing was prioritized for further development in partnership with PATH
- Identified additional needs for training to support all manufacturers
  - Regulatory pathway, manufacturing strategy, influenza vaccination policies
- Prepared clinical roadmap to conduct trials in Vietnam using locally produced vaccine
- Formed collaboration with MOH to strengthen NRA

Conclusion

Factors for consideration of technology go beyond basic science:

- Technical capacity
  - Robustness of process / substrate
- Company capacity
  - Experience with substrate
- Regulatory capacity
  - Defined regulatory pathway
  - Experience of NRA
- Political capacity
  - Urgency of local need
  - Ability to drive a new process

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- WHO
- PATH – Vietnam
- PATH – US

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